ANIMAL ETHICS COMMITTEE

Standard Operating Procedures

V5.00 – 0124

The Griffith University Animal Ethics Committee ("**AEC**") is a sub-committee of the Research Committee. Many of the standard operating procedures for the AEC are described in the University 's online training module *Committee Skills.* This document outlines those operating procedures which are specific to the AEC.

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1.0 Authority

Griffith University has established the Animal Ethics Committee (in this document, referred to as the "**AEC**" or the "**Committee**") to discharge the functions described in the Constitution of the Committee.

2.0 Reporting

Reporting obligations of the AEC are set out in its Constitution.

3.0 Monitoring and review of compliance with the Code

Griffith University will regularly monitor and review institutional compliance with the Code by:

(i) ensuring that an independent external review is conducted at least every four years to assess the University's compliance with the Code, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities under the Code;

(ii) conducting an annual review of the operation of the AEC; and

(iii) conducting an annual review of the effectiveness of its processes regarding complaints and non-compliance.

4.0 Policy and administrative support

The Constitution requires that the Director, Office for Research appoint a Secretary to the Committee. The Secretary is not a Member of the Committee and does not have voting rights, but has rights of audience and debate at AEC meetings.

The role of the Secretary includes the following tasks:

- preparing agendas and minutes for AEC meetings
- facilitating proper process in relation to Committee activities including ensuring that meetings are quorate;
- receiving and forwarding correspondence to AEC Members, as appropriate, such as proposals, reports and variations to approved projects;
- conducting a pre-review of proposals submitted to the AEC to identify any major flaws in applications and provide feedback to the applicants;
- providing commentary and advice to assist in the consideration of matters before the AEC and/or AEC Executive;
- providing advice to senior staff of the University on the governance of animal research ethics, regulatory requirements, and compliance issues;

- providing advice and assistance directly to researchers and supervisors, where appropriate;
- maintaining the University's register of ethics approvals;
- maintaining a Conflict of Interests register in respect of AEC Members;
- coordinating the inspection of on and off campus animal facilities; and
- assisting in the preparation of internal and external reports, submissions and other corporate documents, as requested by the Chairperson.

5.0 Meeting procedures

As set out in the Constitution, an annual meeting schedule for AEC is determined at the end of the preceding year. Generally, the AEC will meet at least 9 times a year.

5.1 Committee papers

There are standard agenda items to assist the AEC in the consideration of the following matters:

(i) Applications for ethics approval or variation requests;

(ii) Reporting on actions taken on conditional or provisional approval and Committee ratification or modification of such actions;

(iii) Reporting on AEC Executive action in relation to requests for minor modifications to existing ethics approval, and subsequent Committee ratification or modification of such actions; and

(iv) Review of reports on existing approved projects and determination that the project may continue, be suspended, require modification or be discontinued.

5.2 Distribution of Committee papers

To enable appropriate consideration, any matters for consideration by the Committee (such as applications for ethics approval) must be received by the Secretary of the AEC by the submission deadline for the upcoming meeting.

Committee papers will be distributed at least 7 days prior to the meeting date.

5.3 Quorum

As set out in the Constitution, a quorum constitutes at least one Member from each of the membership categories A, B, C and D. Categories C and D together must represent at least one-third of those Members present. When a face-to-face meeting is not possible, a quorum may be established through the use of online meeting platforms. A quorum is required for all Committee decisions.

5.4 Conduct of meetings

Meetings of the AEC follow the distributed agenda, and discussion and debate are directed through the Chair. Nevertheless, formal standing orders do not apply to the conduct of the meeting, and debate is conducted in an informal manner.

5.5 Basis for the consideration of issues

Griffith University is committed to transparent and consistent review of proposed animal use in accordance with legislative requirements, with the outcomes promptly communicated to the applicants. The AEC is committed to working collaboratively with researchers and teachers to facilitate excellent and ethical research and teaching.

The deliberations of the AEC and other reviewers must be based upon and consistent with the provisions of the Code, the Act and other regulatory and University policy requirements referred to in the AEC Constitution. Members are required to carefully consider proposed research, policy and other matters, with reference to the above guidelines, policies and regulations. Any review decision and/or advice must be based upon these documents.

5.6 Method for reaching a decision

Wherever possible, Committee decisions should be made on the basis of consensus (as per clause 2.3.11 of the Code). Each Member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the Committee is ethically acceptable (as per clause 1.3 of the Code) and meets the requirements of the Code.

Clause 2.3.12 of the Code requires that for decision making, Members with a conflict of interest (eg. any Member of the AEC listed as an investigator on the application before the Committee) must withdraw from the meeting until that matter is decided. Once such Members have withdrawn, the remaining Members must constitute a quorum. Further guidance on managing conflicts of interest is set out in section 11.0 below.

A Committee Member who feels they need to consult a person who has specialised knowledge before making a decision should raise their questions or concerns with the AEC Chairperson. The Committee Member must identify the person or type of person with whom they wish to consult, their reasons for wanting to consult that person and the issues and questions they wish to discuss. The Chairperson may approve or deny such request, and may impose such conditions on approval as the Chairperson, in their absolute discretion, thinks fit. Confidentiality must be rigorously maintained and persons outside the AEC who are not Griffith staff members, but who are consulted on AEC matters, may be asked to sign a confidentiality agreement in a form acceptable to Griffith.

5.7 Decisions

After the examination of a written proposal concerning the use of animals for scientific purposes the Committee shall:

(i) Approve the proposal;

(ii) Request minor revisions;

(iii) Request a thoroughly revised resubmission; or

(iv) Reject the proposal,

provided that approval shall only be given to research or teaching for which the use of animals is ethically acceptable and which conform to the requirements of the Code. The Committee will consider factors including ethics, the impact on the animal(s) and the anticipated scientific or educational value. The AEC may also raise issues about the validity of the design of a research proposal including statistical validity of results.

5.8 Communicating the outcomes

After each meeting of the AEC, the Secretary will:

(i) email the outcomes of committee decisions to the proponents (normally within five working days of receiving an outcome of a review); and

(ii) upon receiving a response to a notification of conditional or provisional approval, provide the response and relevant documentation to the Chair, AEC Executive or Committee as specified by the Committee at the meeting where the application was considered.

In the interests of timeliness, efficiency and sustainability, the described communication processes make use of email and the internet. The *Animal Ethics Approval, Conditional Approval or Provisional Approval Notification factsheet* is a source of further information in relation to the processing of applications for ethics approval.

6.0 Minutes

Minutes of each meeting will be distributed to Committee Members. Minutes provided for inclusion in the agenda of Research Committee will not include the names of Members.

7.0 Format of submissions of applications for ethics approval

To be considered for review, an application must be submitted on the correct form within the Research Information Management System (RIMS), with appropriate signatures and attachments, and conform to any other requirements specified by the University. An incomplete application or an application made using the incorrect form may be returned unprocessed.

Unless the proponent presents a compelling argument for action to the contrary, applications submitted after the due date for the meeting will normally be held over and considered at the Committee's next meeting.

8.0 Administrative Processes

8.1 Submission of an application to scheduled meetings

1. Applications are submitted and signed off electronically via RIMS on or before the submission deadline of the AEC meeting. Submission deadlines are available at https://www.griffith.edu.au/research/research-services/research-ethics-integrity/animal/animal-ethics-applications.
2. Upon receipt, an acknowledgement letter is sent to the Responsible Investigator and copied to animal-ethics@griffith.edu.au.
3. Committee papers will be distributed at least 7 days prior to the meeting date.
4. Following the assessment of an application by the AEC, the AEC Secretary notifies the Responsible Investigator in writing of the approval or other decision regarding the application. Where issues have been identified by the Committee, the Responsible Investigator is notified by email, with replies referred to the full Committee, AEC Executive or AEC Chair as appropriate, who may approve the application if satisfied that the reply addressees the concerns of the full AEC.
5. Where animal holding facilities are involved, the animal facilities manager should also be notified of any approved projects. Where procedures involved may require oversight by a veterinarian, any relevant Consultant Veterinarian may be notified as appropriate. Research cannot proceed until full or conditional approval has been granted.
6. The AEC Secretary notifies the Responsible Investigator in writing of final approval and provides an animal ethics approval certificate outlining details of the approval.
7. The outcome of the decision and details of each application are recorded within RIMS.

8.2 Submission of an application approved by another AEC

1. Prior Review application forms may be submitted electronically via RIMS at any time.
2. Upon receipt, an acknowledgement letter is sent to the Responsible Investigator and copied to animal-ethics@griffith.edu.au.
    a. Following the consideration of the application by the AEC Executive or AEC, the AEC Secretary notifies the Responsible Investigator in writing of the ratification or other decision regarding the application. Where issues have been identified by the Committee, the Responsible Investigator is notified by email, with replies referred to the full AEC, AEC Executive or AEC Chair as appropriate who may approve the application if it is satisfied that all the concerns have been addressed.
3. The AEC Secretary notifies the Responsible Investigator in writing of final ratification.

4. The outcome of the decision and details of each application are recorded within RIMS.

Please refer to the "Prior Review Factsheet - Ratification of projects approved by other Animal Ethics Committees" available at: https://www.griffith.edu.au/data/assets/pdf_file/0029/209756/Prior-Review-Factsheet-Ratification-of-projects-approved-by-other-AECs.pdf for more information on projects involving more than one AEC.

8.3 Submission of a variation form to scheduled meetings

1. Variation requests are submitted via RIMS on or before the submission deadline of the AEC meeting. Submission deadlines are available at https://www.griffith.edu.au/research/research-services/research-ethics-integrity/animal/animal-ethics-applications.
2. Upon receipt, an acknowledgement email is sent to the Responsible Investigator and copied to animal-ethics@griffith.edu.au.
3. Committee papers will be distributed at least 7 days prior to the meeting date.
4. Following the assessment of the variation request, the AEC Secretary notifies the Responsible Investigator in writing of the approval or other decision regarding the variation request. Where issues have been identified by the Committee, the Responsible Investigator is notified by email, with replies referred to the AEC Executive or AEC Chair as appropriate who may approve the application if it is satisfied that the reply addresses the concerns of the full AEC.
5. Where animal holding facilities are involved, the animal facilities manager should also be notified of any approved variations. Where procedures involved may require oversight by a veterinarian, any relevant Consultant Veterinarian may be notified as appropriate. The varied research protocol cannot proceed until full or conditional approval has been granted.
6. The AEC Secretary notifies the Responsible Investigator in writing of final approval.
7. The outcome of the decision and details of each application are recorded within RIMS.

8.4 Consideration of a variation form between scheduled meetings

In limited circumstances, the AEC Executive may consider variation requests between scheduled AEC meetings. The power is limited to the following types of requests:

(i) requests for approval of a minor amendment (variation) to an approved protocol which is not likely to cause harm to animals, such as a one year extension of an existing approval or changes to project personnel; and

(ii) requests that address the need to change protocols urgently in order to improve animal welfare or avoid compromising animal welfare.

Interim decisions made by the AEC Executive in response to such requests are presented for ratification or modification by the Committee at the next scheduled AEC meeting. The following administrative process applies to such requests:

1. Variation requests for consideration by the AEC Executive (ie. between scheduled AEC meetings) are submitted via RIMS.
2. Upon receipt, an acknowledgement email is sent to the Responsible Investigator and copied to animal-ethics@griffith.edu.au.
3. The AEC Secretary contacts the AEC Executive via email and requests the consideration of the variation between scheduled meetings.
4. After considering the request, the AEC Executive can approve the variation, request further information from the applicant(s), or refer the request to the AEC.
5. Following the assessment of the variation request, the AEC Secretary notifies the Responsible Investigator in writing of the approval or other decision regarding the variation request. Where issues have been identified by the AEC Executive, the Responsible Investigator is notified by a letter. The reply is referred to the AEC Executive who may approve the application if it is satisfied that the reply addressees the concerns raised.
6. Where animal holding facilities are involved, the animal facilities manager should also be notified of any approved variations. Where procedures involved are likely to require oversight by a veterinarian, any relevant Consultant Veterinarian may be notified as appropriate. The varied research protocol cannot proceed until full or conditional approval has been granted.
7. The AEC Secretary notifies the Responsible Investigator in writing of the interim decision by the AEC Executive.
8. The AEC Secretary registers the interim decision and details of each application in RIMS.
9. The variation request and the interim decision made by the AEC Executive are considered by the AEC at its next scheduled meeting, so that the decision can be ratified or modified by the Committee.
10. The AEC Secretary notifies the Responsible Investigator in writing of the AEC's decision (ie. whether the interim decision was ratified or modified).
11. The AEC Secretary registers the final decision in RIMS.

8.5 Submission of Unexpected adverse events, Annual, Progress and Final Reports

Investigators must ensure that records of the use and monitoring of animals used for scientific purposes are maintained and any unexpected adverse events are immediately reported to the AEC through the Secretary. Investigators should consult the Griffith Guidelines for Animal Care and Use in Teaching and Research for detailed guidance. Investigators must maintain records of the care and use of animals, and make such records available to the institution, the AEC and authorised external reviewers. Under a particular AEC approval, records must include:

(i) the origin or source of the animals and provisions for the animals at conclusion of their use;

(ii) the number of animals used;

(iii) details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes;

(iv) the condition of the animal, any adverse impact on animal wellbeing and actions taken as a result;

(v) names of people performing the procedures and entering the records; and

(vi) names and contact details of people responsible for monitoring and responding to emergency incidents.

The AEC will advise Investigators of any additional information to be recorded. These records must be available for audit by the AEC at any time, including during random facility and protocol audits.

Investigators will be required to provide an annual report for each active protocol by 25 January of each year. The AEC Secretary will follow up with Investigators to ensure all reports are provided by the due date.

Where the Responsible Investigator or Investigators have other ongoing or completed protocols and the annual report or other reports specifically requested by the Committee are overdue, the AEC may suspend current approvals and/or withhold approval of further research applications or amendment requests.

9.0 Monitoring of research

In line with clauses 2.3.17 to 2.3.23 of the Code, the University has established a number of strategies to monitor the care and use of animals. These include:

(i) researchers completing an annual and/ or final report upon completion of the project. Completed reports are received and reviewed by the Secretary, who keeps a record of the report and adds the report to the agenda of the following AEC meeting for review by a Member; and

(ii) the AEC randomly selects a number of projects each year for audit. This audit process is described in the Griffith Guidelines for Animal Care and Use in Teaching and Research.

The following additional strategies are used to ensure that projects do not proceed without ethical approval and to check for projects that may have proceeded in the absence of approval:

(i) the Finance Office will not create an account for a research project which uses animals without either confirmation of ethical approval or alternative advice from Office for Research; and

(ii) Griffith Graduate Research School will immediately advise the Office for Research if it appears, at any stage during candidature up to the point of confirmation, that a HDR project has proceeded without the required ethics approval.

(iii) Animals cannot be purchased through the Biosciences Resources Facilities database without prior animal ethics approval.

Further information about the University's monitoring processes, including the handling of unexpected adverse events, can be found in the *Guidelines for Animal Care and Use in Teaching and Research*.

10.0 Confidentiality

As set out in the Constitution, each Member of the AEC is required to sign a "**Membership Deed**" (Attachment 2) confirming (among other things) that they will not inappropriately disclose any confidential information.

This undertaking means that, outside of a meeting, Members should only discuss matters relating to the Committee's deliberations if:

(i) they are discharging a delegated or official responsibility of their membership (e.g. an Animal Ethics Advisor discussing with a head of element a pattern of problems with applications submitted from that element); or

(ii) disclosure is required in relation to official University business.

Provisions for consultation with persons with specialised knowledge who are not Committee Members, including confidentiality requirements, are set out in section 5.6 above. Members must follow these procedures at all times to ensure that the confidentiality of information received by them in the course of their membership of the AEC is not compromised.

The University maintains records in relation to ethics applications and related activity. These records are considered confidential and access to them is restricted. If a Member wishes to access these records outside the context of an AEC meeting, they should contact the Chair in the first instance who will refer the matter to the Manager Research Ethics and Integrity.

11.0 Conflicts of interest

The Membership Deed referred to in section 10.0 above also requires each Member to confirm that they will disclose any conflict of interest, whether actual, potential or perceived.

This undertaking means that Members must identify and disclose any conflict of interest, including family or other personal relationship/s, as outlined in the University policies on Conflict of Interest and Personal Relationships in the Workplace, which may exist, either in

general in relation to Committee business or specifically in respect of any of the individual items on a given agenda. When an interest has been declared, the Committee may resolve (by decision made on a majority basis) that the Member:

- leaves the meeting while the item of business is discussed; or
- participates in the discussion but withdraws from the meeting before the decision.

All declarations of interest will be recorded in the minutes, together with any ensuing action.

The Code requires that for decision making, Members with a conflict of interest must withdraw from the meeting. Once such Members have withdrawn, the remaining Members must constitute a quorum (see clause 2.3.12 of the Code).

12.0 Personal Information

The Membership Deed referred to in sections 10.0 and 11.0 above also requires Members to confirm that they will handle personal information in accordance with the University's Privacy Plan. The Privacy Plan is published at: http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan.

Personal information is defined as information or an opinion, including information or an opinion forming part of a database, whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

This undertaking means that Members must not use or disclose personal information unless the person about whom the information was collected is aware of, or has consented to, that use or disclosure.

13.0 Insurance cover for Members

The University's insurance policies cover the good faith actions of duly appointed Members of the AEC, while such persons are engaged in activities officially organised and controlled by the University.

14.0 Fees

The University does not apply a processing fee for the consideration of proposals for ethics approval.

15.0 External research

The AEC does not process ethics applications which do not relate to Griffith University research or teaching.

16.0 Member training

Griffith University is committed to the training and ongoing development of the Members of the AEC. The University will support the attendance of a number of Committee Members at the annual Australian and New Zealand Council for the Care of Animals in Research and Teaching conference, subject to budget availability. The University will also support, subject to budget, relevance and operational considerations, the attendance of Members at other training, development and networking opportunities.

New Animal Ethics Committee members undergo a formal induction process as part of their initial training. Members are provided with a link to a new member kit containing a number of training resources. The resource kit includes the following documents:

1. AEC Constitution.
2. The AEC Standard Operating Procedures (this document).
3. The Australian Code for the Care and Use of Animals in Research and Teaching (2013, updated 2021).
4. The Griffith University Guidelines for Animal Care and Use v2.1.
5. The University Conflict of Interest Policy and disclosure statement form.
6. DAF Proposal Assessment Checklist.
7. AEC Induction Package, ANZCCART.

New members are required to complete an online Animal Ethics Committee member training course, which consists of 6 modules and several knowledge checks in each module. Completion of this course must occur every 3 years as part of the training renewal.

The course modules include:

1. Introduction to the Use of Animals in Research and Teaching.
2. The Code's Governing Principals
3. Responsibilities
4. Animal Wellbeing
5. The Animal Ethics Committee
6. Best Practice Methodology and Reporting of Animal Studies.

New members and investigators alike are now strongly encouraged to complete in addition to the above, the ANZCCART COMPASS (Competency Passport) online training course.

17.0 Complaints, Investigations and Appeals

Please refer to Booklet 01 of the Animal Ethics Manual "Processes for responding to complaints, alleged breaches of ethical standards, or appeals against decisions" available at: https://www.griffith.edu.au/research/research-services/research-ethics-integrity/animal/animal-ethics-applications.

Attachments:

1. *Constitution of the AEC*
2. *Membership Deed (Commitment to abide by the Constitution and Standard Operating Procedures of the Committee)*